Endovascular Treatment of Internal Carotid and Vertebral Artery Aneurysms Using a Novel Pericardium Covered Stent

I. VULEV[1], A. KLEPANEC[1], R. BAZIK[1], T. BALAZS[1], R. ILLES[2], J. STENO[2]

[1] *Department of Diagnostic and Interventional Radiology, National Institute of Cardiovascular Diseases; Bratislava, Slovakia*
[2] *Department of Neurosurgery, Comenius University, Derer's Faculty Hospital; Bratislava, Slovakia*

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Summary

Intracranial aneurysm is a fairly common (often asymptomatic) condition. Subarachnoid hemorrhage associated with aneurysmal rupture is a potentially lethal event with a mortality rate as high as 50 percent and a high rate of disability among those who survive the initial hemorrhage, such that recently published guidelines support treatment of intracerebral aneurysms. The current treatment options include surgical clipping and endovascular treatment, but these are not without significant problems. Despite the trend toward endovascular treatment the rate of recurrence and complications is high. Current published evidence of the use of covered stent is limited to stents covered with polytetrafluoroethylene. It is now recognized that mammalian extracellular matrix represents an excellent scaffold material suitable for many therapeutic applications and glutaraldehyde treated pericardium has been widely used for many years due to its desirable features such as low immunogenicity and durability. This report describes the first published experience with the Aneugraft Pericardium Covered Stent (ITGI Medical, OR Akiva, Israel) in the treatment of internal carotid and vertebral artery aneurysms in three patients. In all three cases, the implantation of this novel device has resulted in successful closure of aneurysms.

Introduction

Intracranial aneurysm is a fairly common condition that is often asymptomatic until the time of rupture. Subarachnoid hemorrhage associated with aneurysmal rupture is a potentially lethal event with a mortality rate as high as 50 percent. Many patients who survive the initial hemorrhage have permanent disability [1]. Some studies have estimated the prevalence as high as 6% [2]. Recently published guidelines support treatment of intracerebral aneurysms [3].

The current treatment options include surgical clipping and endovascular treatment, but these are not without significant problems [4]. For instance, a randomized, multicentre trial compared the safety and efficacy of endovascular coiling with standard neurosurgical clipping for aneurysms found that the outcome in terms of survival free of disability at 1 year is significantly better with endovascular coiling [5]. In addition, neurosurgery is associated with significantly longer length of stay and significantly higher total hospital charges [6].

Despite the trend toward endovascular treatment the rate of recurrence and complications is high. Recurrence is seven times more likely with coils than clipping, aneurysm sac perfusion persists in completely occluded aneurysms (even when initial or follow-up angiography shows closure) [7,8]. Bleeding from incompletely coiled aneurysms is a well-documented threat and rerupture frequently occurs [9-12].

The principal goal of the flow divertor is placement in the parent artery in order to reconstruct the vessel wall [13]. The major complications with flow divertors have been found to be perforator artery stroke, aneurysm re-rupture, and in-stent stenosis and thrombosis [14,15].

Covered stents have also shown better closure and shorter procedure time in clinical investigations [16]. Current published evidence of

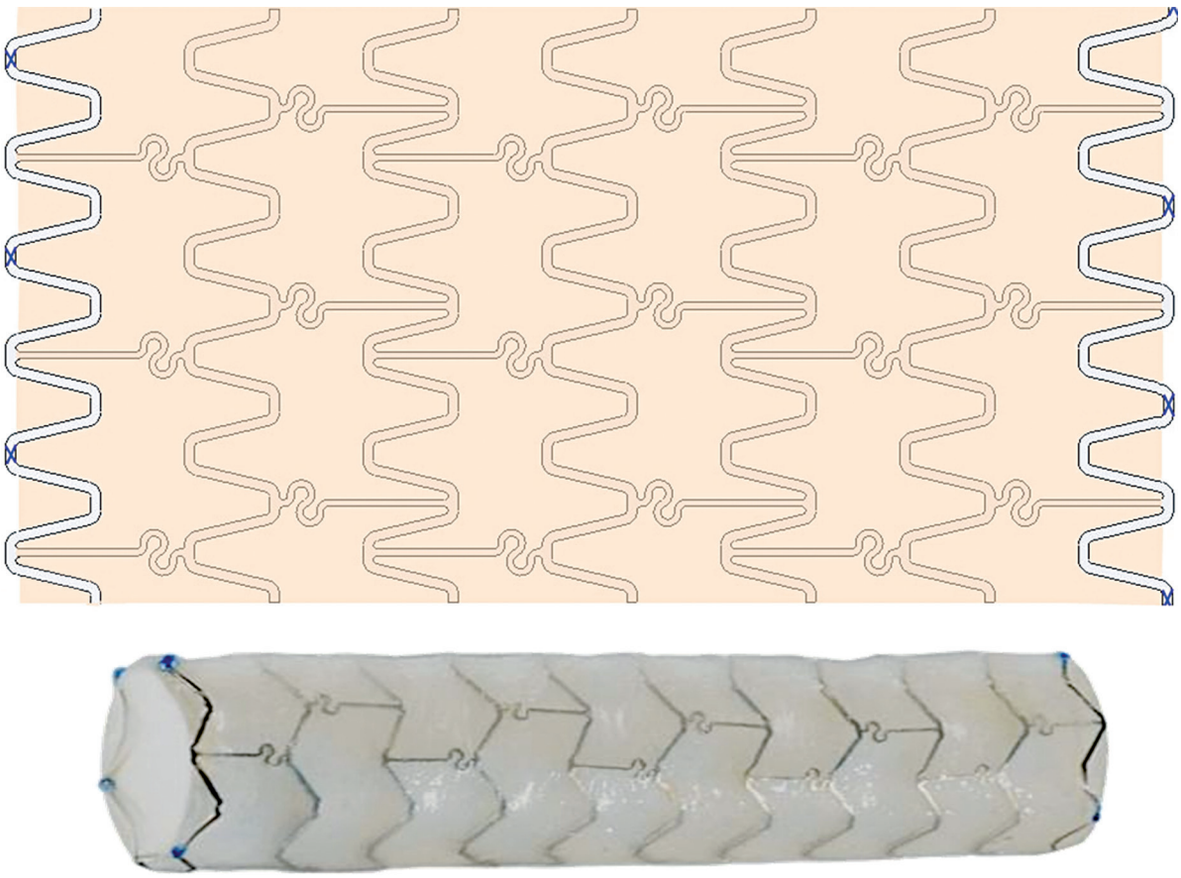

Figure 1 Configuration of a novel pericardium-covered stent (PCS).

the use of covered stent is limited to stents covered with polytetrafluoroethylene (PTFE) [17]. Synthetic materials are used in biological settings with limited success. Studies have shown that polyester covered stent graft with 50% re-stenosis and e-PTFE covered stent with 24% re-stenosis in a sheep iliac model [18]. It has also been shown that PTFE retards endothelization and that Dacron is prone to infection, due to adherence to and survival of bacteria on its rough surface [19]. Other materials are also used as coverings in the context of medical devices. Glutaraldehyde-treated pericardium has been widely used for many years due to its desirable features such as low immunogenicity and durability [20-25]. It has been shown that there is significantly less inflammatory cytokine, significantly less antibody response and inflammatory response compared to un-crosslinked decellularized pericardium [26]. It is now recognized that mammalian extracellular matrix represents an excellent scaffold material suitable for many therapeutic applications [27]. In Neurosurgery, serous sheets are used as dural substitute. An investigation involving 200 patients undergoing a surgical procedure with the application of horse pericardium as a dural prosthesis found that they are free from antigenic effects and do not produce any toxic catabolites [28]. The pericardium proved to be resistant to surgical suture, impermeable to cerebrospinal fluid, transparent and does not cause any clinical evidence or radiological artifacts. Pericardium has also shown decreased intraoperative suture line bleeding compared to Dacron [29].

A CE marked coronary stent covered with pericardium (Aneugraft: ITGI Medical limited, Or Akiva, Israel) is available, which so far shows promising clinical results. The pericardium covered stent (PCS) is a percutaneous implantable device consisting of a 316 L stainless steel stent covered by a 100 μ thick equine pericardium cylinder which makes this device flexible and trackable. It is available in diameters of 2.5 mm, 3.0 mm, 3.5 mm, and 4.0 mm, and lengths of 13, 18, 23 and 27 mm. The stent

is mounted on a balloon catheter. The device can be seen in Figure 1. It has proved to be safe and effective in two registries [30], and there is also published evidence attesting to this in other indications [31-43]. This report describes the first published experience with the PCS in the treatment of internal carotid and vertebral artery aneurysms in three patients.

Case 1

A 52-year-old woman with a pulsatile palpable mass in the left retromandibular space was referred to our hospital. Computed tomography angiography (CTA) revealed a giant false aneurysm of the left cervical segment of the internal carotid artery (ICA) that was probably due to arterial injury caused by an elongated styloid process. CTA revealed significant elongation and tortuosity of the left and right proximal ICA and a large supra-ophthalmic aneurysm of the right ICA (Figure 2). A four-step, multidisciplinary therapeutic plan combining surgical and endovascular modalities was selected: (i) resection and straightening of proximal tortuosity of the right ICA; (ii) endovascular coiling of intracranial aneurysms (Figure 3); (iii) resection and straightening of the proximal left ICA; and (iv) endovascular treatment of the false aneurysms in the left retromandibular space using PCS. Before implantation of the PCS, the patient was given 100 mg aspirin and 300 mg clopidogrel. Right femoral access was used and digital subtraction angiography (DSA) of the left carotid artery confirmed the findings of the CTA (Figure 4A,B). A 6-F guiding catheter (Guider Softip™ XF, Boston Scientific Corp., Fremont, CA, USA) was advanced in the distal part of the common carotid artery (CCA). A 0.014 guidewire (Synchro, Boston Scientific Corp., Fremont, CA, USA) was then passed distal to the neck of the aneurysm. The length of the aneurysm neck necessitated two PCS, and resulted in complete exclusion of the aneurysm demonstrated on post-procedure angiography (Figure 4C).

Case 2

A 44-year-old woman was referred to our hospital after suffering a subarachnoid hemorrhage. Coiling of a small aneurysm of the communicating segment of the left ICA had been done. A giant (20 ← 18 mm), large-neck aneurysm was discovered on CTA at the intradural fourth segment of the left vertebral artery (VA) proximal to the posterior inferior cerebellar artery (PICA). Endovascular treatment was considered to be first-line treatment for this VA aneurysm. The patient received 100 mg aspirin and 75 mg clopidogrel for three days before the procedure. Right femoral access was used and a 6-F guiding catheter (Neuron, Penumbra Inc, San Leandro, California, USA) advanced to the V3 segment of the left VA. DSA showed a giant, large-neck aneurysm of the V4 segment of the VA (Figure 5A). After passage of a 0.014 guidewire (Synchro, Boston Scientific Corp., Fremont, CA, USA) distal to the aneurysm neck, a 4 ← 27 mm PCS was deployed and inflated to 12 atm. The aneurysm was completely excluded and this was demonstrated at control angiography (Figure 5B). Follow-up CTA at three months demonstrated complete exclusion and shrinkage of the aneurysm to 18 ← 16 mm (Figure 6).

Case 3

An 85-year-old woman was admitted to our hospital for endovascular therapy of a symptomatic large-neck aneurysm of the cervical segment of the ICA subsequent to a stroke in the left middle cerebral artery (MCA). The patient was pre-medicated with 100 mg aspirin and 75 mg clopidogrel for three days before the procedure. Endovascular treatment was undertaken after gaining access via the femoral artery and placement of a 6-F guiding sheath (Guider Softip™ XF, Boston Scientific Corp., Fremont, CA, USA) in the CCA. DSA confirmed the CTA findings of an aneurysm of the cervical segment of the ICA (Figure 7A,B). A 0.014 guidewire (Synchro, Boston Scientific Corp., Fremont, CA, USA) was passed distal to the aneurysm and a PCS (4 ← 27 mm) advanced over the wire and placed in the optimal position. The balloon was slowly inflated to 10 atm and the PCS successfully deployed. Control DSA confirmed complete exclusion of the aneurysm with preservation of ICA patency (Figure 7C).

Discussion

Different endovascular techniques have been used in the treatment of wide neck intracranial and extracranial carotid and vertebral

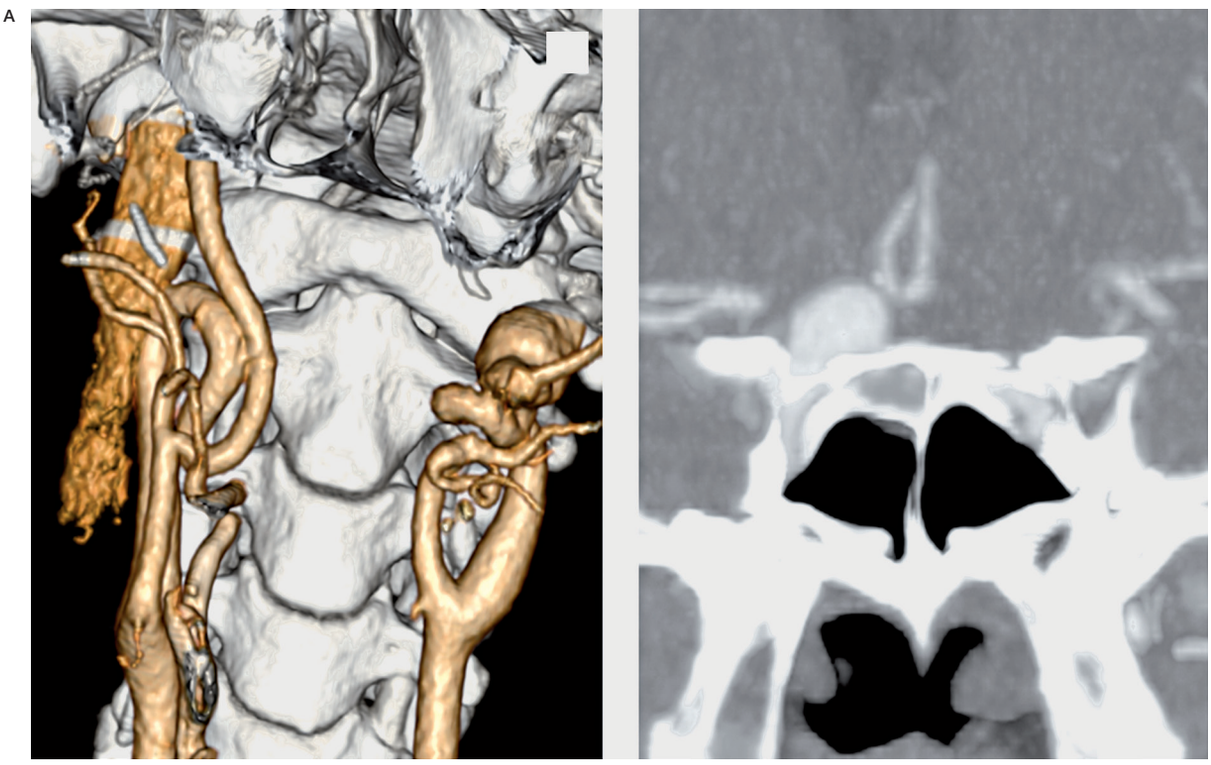

Figure 2 CTA finding of a styloid process causing a false aneurysm of the left ICA, elongation of both proximal parts of the ICA and a large aneurysm of the supra-ophthalmic part of the right ICA (A,B).

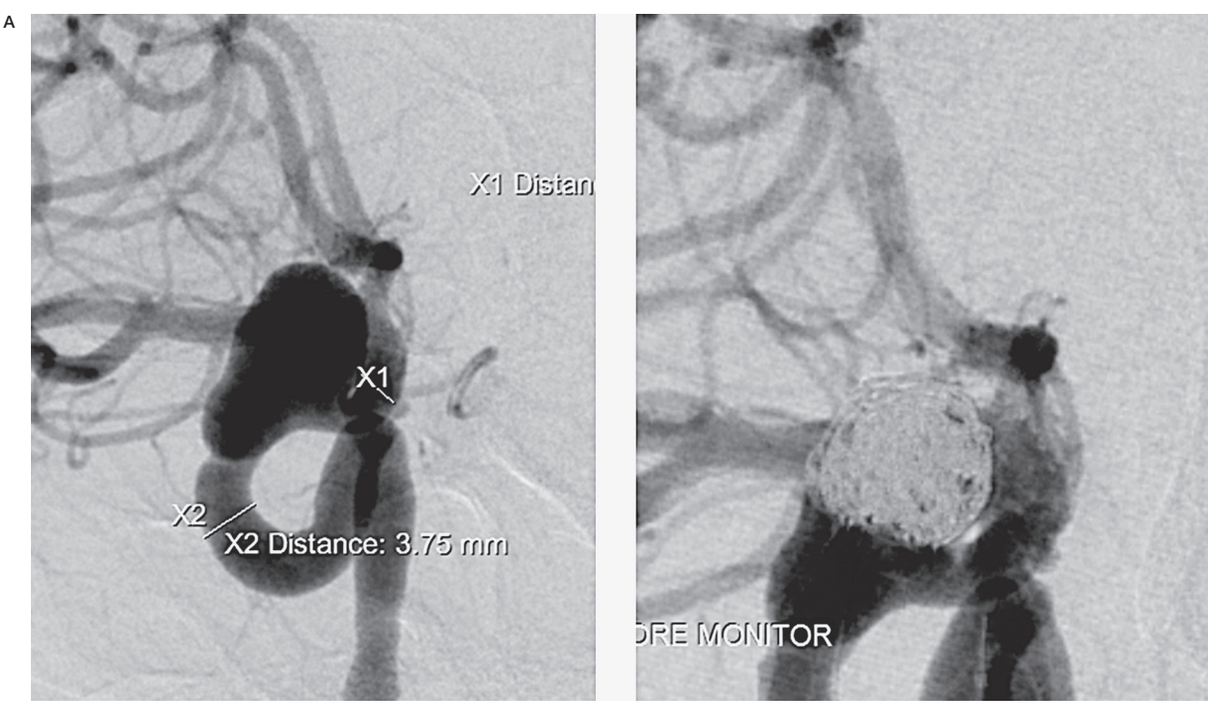

Figure 3 DSA before coiling of the aneurysm of the supra-ophthalmic part of the right ICA (A) and after endovascular treatment (B).

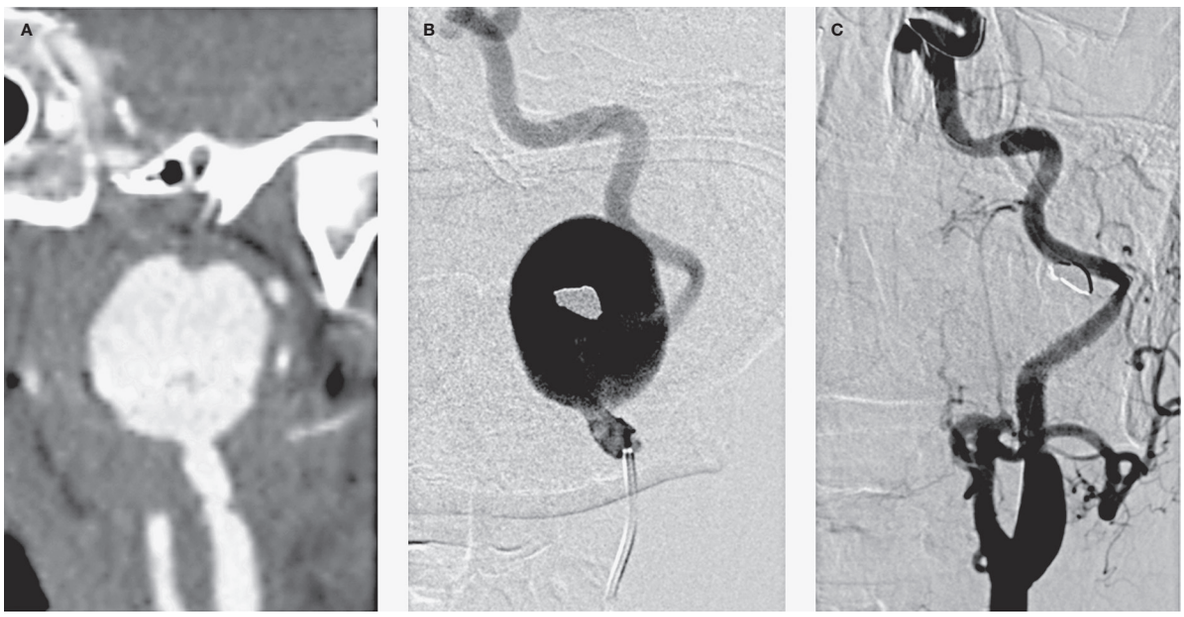

Figure 4 CTA (A) and DSA (B) of a giant false aneurysm of the cervical segment of the left ICA and post-procedure angiography after placement of a covered stent (C).

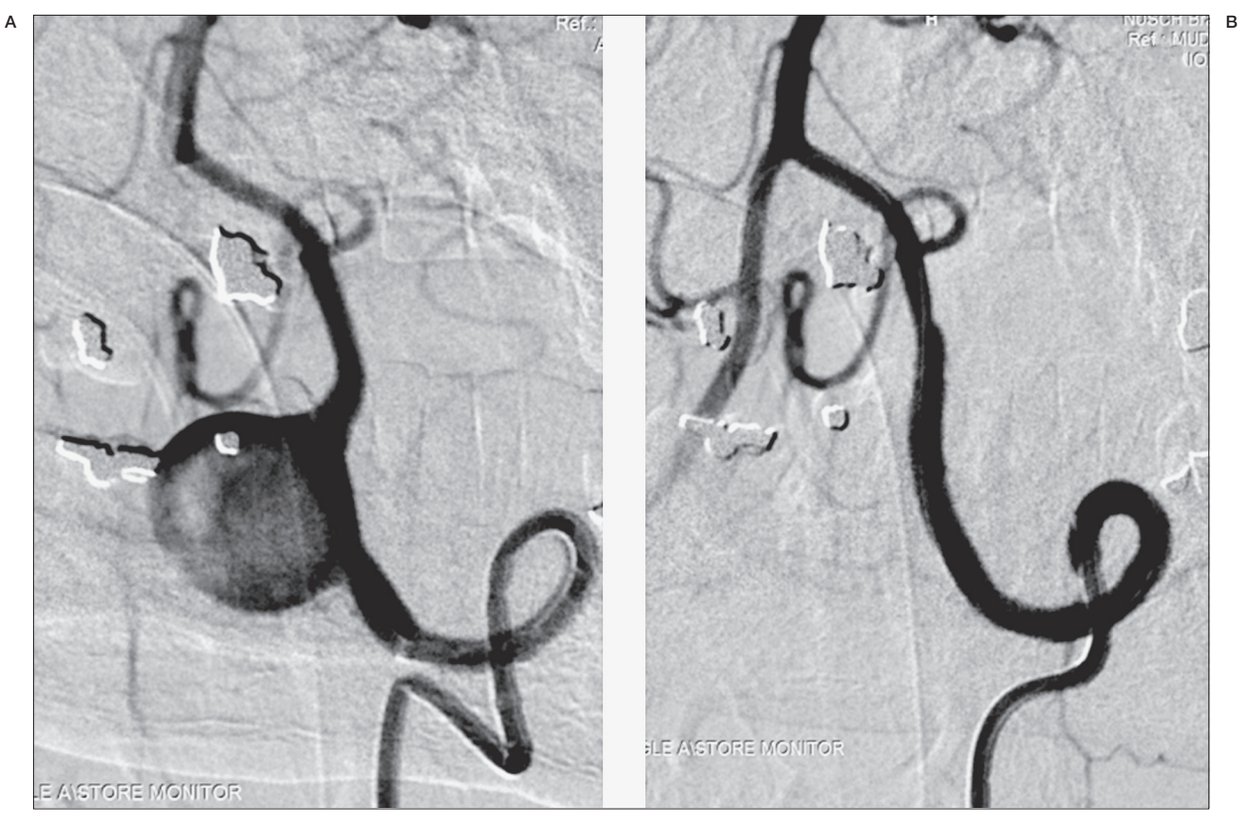

Figure 5 Preoperative DSA of a giant aneurysm of the V4 segment of the left VA (A) and DSA after placement of a covered stent with no filling of the aneurysm (B).

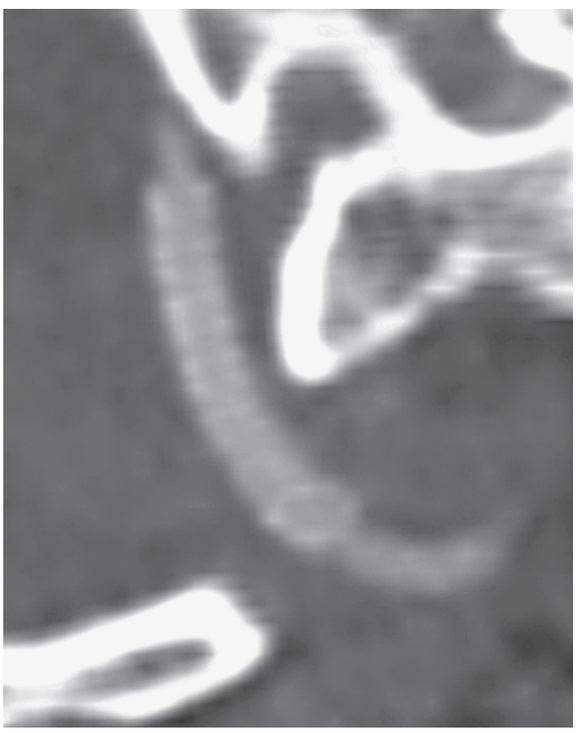

Figure 6 Three-month follow-up CTA showing aneurysm exclusion, a patent covered stent with no intimal hyperplasia, and aneurysm shrinkage.

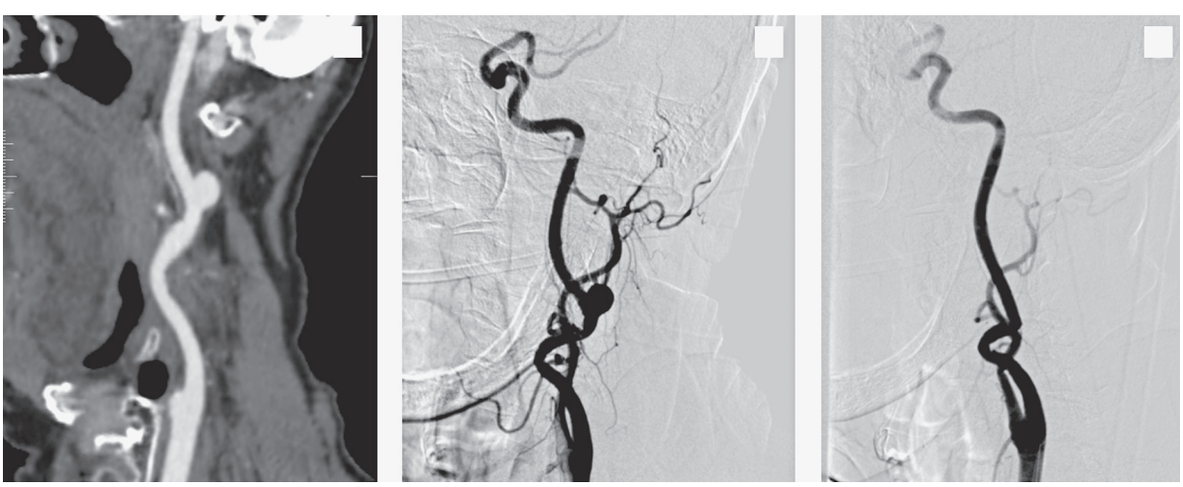

Figure 7 CTA (A) and DSA (B) before endovascular treatment of an aneurysm of the left cervical segment of the ICA and final angiogram after implantation of a covered stent (C).

aneurysms. The use of covered stents represents one of the treatment options. A covered stent, the Jostent Graftmaster (Abbott Laboratories, Abbott Park, ILL, USA), has been used for aneurysms up to the ophthalmic artery or up to the vertebrobasilar junction [44,45]. The Graftmaster has also been used for carotidocavernous fistulas and dissections [46]. Other types of covered stent have also been used for the treatment of internal carotid and vertebral aneurysms: Fluency stent (Bard Peripheral Vascular, Tempe, AZ, USA), Gore Viabahn (W.L. Gore & Assoc, Newark, DE, USA), iCast (Atrium Medical, Hudson, NH) and Wallgraft (Boston Scientific, MA, USA) [47,48].

Covered stents have shown better closure and shorter procedure time in clinical investigations: 89 patients with cranial internal carotid artery aneurysms were treated nonrandomly with covered stents (n = 43) or coil emboliza-

tion (n = 46). The initial angiographic results showed 80.9% complete occlusion in covered stents and 52.2% in coil patients (P = 0.004). The six month angiographic results indicated 95.1% and 48.9% respectively (P < 0.001). In addition, the average procedure time was shorter in the covered stents group [49]. Stentgraft has also been used for the treatment of ruptured fusiform aneurysm of intracranial vertebral artery and vertebral artery dissecting aneurysms [50,51]. There is published evidence of good clinical results of the use of pericardium covered stent in degenerated saphenous vein grafts [30,36,37,42], coronary artery perforations [38,39], coronary artery fistulae [40], hypertrophic obstructive cardiomyopathy [41], aneurysm [32-34,37,39,42,43], acute myocardial infarction [35,52] and iatrogenic radial arteriovenous fistula [31].

The primary drawback in the use of this technology is the potential for blockage of side branches. This is something that the operator must consider prior to treatment. The other drawback with this technology is the lack of published evidence. As mentioned above, it is reasonable to expect that the biological tissue is superior to synthetic tissue, but the absence of published formal clinical investigations (it has even been performed as well as autologous tissue in some animal models) [53,54], may preclude the widespread use of this device. The potential advantage is that whilst slightly bulkier than a bare metal stent, it is thin and flexible and offers better deliverability than other covered stents [55].

In conclusion, the Aneugraft configuration allows for a single stent, single layer cover making for a trackable and flexibile device. This also allows, complete occlusion of the aneurysm, fistula or dissection in one action. We describe the first cases of use of a PCS in the treatment of wide-neck aneurysms of the ICA and VA. More detailed clinical studies will need to be conducted to confirm the overall performance and long-term effect of the PCS in the treatment of extracranial and intracranial aneurysms of the internal carotid artery or vertebral artery.

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Ivan Vulev, MD, PhD, MPH
National Institute of Cardiovascular Diseases
Pod Krásnou Hôrkou 1 - 83848 Bratislava 37, Slovakia
Tel. +421 2 59 320 298
E-mail: ivan.vulev@nusch.sk